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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/536,777

09/07/2006

Karl Groke

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535 7590 04/02/2010

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EXAMINER

STONE, CHRISTOPHER R

ART UNIT

PAPER NUMBER

1628

NOTIFICATION DATE

DELIVERY MODE

04/02/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/536,777	Applicant(s) GROKE ET AL.	
	Examiner CHRISTOPHER R. STONE	Art Unit 1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 18-20 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8, 11, 12, 14, 15 and 18-20 is/are rejected.
- 7) ☒ Claim(s) 5, 9, 10 and 13 is/are objected to.
- 8) ☒ Claim(s) 23-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed June 29, 2009, have been fully considered but are moot in view of new grounds of rejection. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 1-15, 18-20 and 23-26 are currently pending and under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-8, 11, 12, 14, 15, 18-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for therapeutic agents comprising 5-hydroxymethylfurfural for the treatment of cancer, methods of preparing said therapeutic agents and methods of treating breast, uterine, esophageal, bladder and lung cancer comprising administering said therapeutic agents, does not reasonably provide enablement for therapeutic agents, which do not comprise the 5-hydroxymethylfurfural for the treatment of cancer, methods of preparing said therapeutic agents and methods of treating breast, uterine, esophageal, bladder and lung cancer comprising administering said therapeutic agents. The specification does not enable

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any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the nature of the invention, (2) the relative skill of those in the art, (3) the breadth of the claims, (4) the amount or direction or guidance presented, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the state of the prior art, and (8) the predictability or unpredictability of the art.

Although the quantity of experimentation alone is not dispositive in a determination of whether the required experimentation is undue, this factor does play a central role. For example, a very limited quantity of experimentation may be undue in a fledgling art that is unpredictable where no guidance or working examples are provided in the specification and prior art, whereas the same amount of experimentation may not

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be undue when viewed in light of some guidance or a working example or the experimentation required is in a predictable established art. Conversely, a large quantity of experimentation would require a correspondingly greater quantum of guidance, predictability and skill in the art to overcome classification as undue experimentation. In *Wands*, the determination that undue experimentation was not required to make the claimed invention was based primarily on the nature of the art, and the probability that the required experimentation would result in successfully obtaining the claimed invention. (*Wands*, 8 USPQ2d 1406) Thus, a combination of factors which, when viewed together, would provide an artisan of ordinary skill in the art with an expectation of successfully obtaining the claimed invention with additional experimentation would preclude the classification of that experimentation as undue. A combination of *Wands* factors, which provide a very low likelihood of successfully obtaining the claimed invention with additional experimentation, however, would render the additional experimentation undue.

The nature of the invention and the breadth of the claims

Claims 1-4, 6-8, 11, 12, 14, 15, 18-20 are drawn to therapeutic agents comprising and not comprising 5-hydroxymethylfurfural for the treatment of cancer, methods of preparing said therapeutic agents and methods of treating breast, uterine, esophageal, bladder and lung cancer comprising administering said therapeutic agents. The invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

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Level of skill in the art

The level of skill in the art is deemed to be high, generally that of a PhD or MD.

Guidance in the specification and Working Examples

The only data in the specification merely demonstrates the ability of a single therapeutic composition, which comprises 5-hydroxymethylfurfural as an active ingredient to treat breast, uterine, esophageal, bladder and lung cancer (p. 19-28 of the instant specification). The specification is silent with regard to the use of compositions which do not comprise 5-hydroxymethylfurfural as an active ingredient to treat breast, uterine, esophageal, bladder and lung cancer. While it is understood that the absence of working examples should never be the sole reason for rejecting a claims as being broader than an enabling disclosure, the criticality of working examples in an unpredictable art, such the treatment of cancer, is required for practice of the claimed invention.

Quantity of experimentation

The quantity of experimentation in the areas of the preparation of compositions intended for use in cancer therapy and methods of treating cancer using such compositions is extremely large given the unpredictability associated with the treatment of cancer (see **The unpredictability of the art and the state of the prior art** heading below).

The unpredictability of the art and the state of the prior art

The prior art teaches that the preparation of compositions intended for use in cancer therapy and methods of treating cancer using such compositions are difficult and unpredictable. The prior art indicates that cancer is a group of maladies not treatable with one medicament or therapeutic regimen. No single chemotherapeutic drug is useful for the treatment of every case of cancer. In fact some cancers do not respond well to any known chemotherapeutic drug (see Oxford Textbook of Oncology, p. 451, Column 2, last paragraph, previously made of record). While the prior art recognizes the therapeutic anticancer activity of compositions comprising alpha-ketoglutaric acid in combination with 5-methylfurfural (see e.g. Groke et al, US 5,006,551, previously made of record), it is silent with regard to therapeutic activity (e.g. anticancer activity) of alpha-ketoglutaric acid alone or in combination with the other claimed composition components (malt, N-acetyl-seleno-L-methionine, N-acetyl-L-methionine, etc.), which as Applicant notes, (Reply filed June 29, 2009, p. 10, first paragraph and p. 13, first paragraph) are not known therapeutic agents. This indicates an extreme art recognized unpredictability with regard to the preparation of compositions not comprising 5-methylfurfural intended for use in cancer therapy and methods of treating cancer using such compositions.

Conclusion

Thus given the instant claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the lack of guidance provided in the specification, and the negative teachings in the prior art balanced only against the high

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skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claims as written.

Allowable Subject Matter

Claims 5, 9, 10 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 23-26 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. STONE whose telephone number is (571)270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CRS

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642